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on June 25, 2004

Glenn P. Ladwig  
Glenn P. Ladwig, Patent Attorney

INFORMATION DISCLOSURE  
STATEMENT

Examining Group 3731

Patent Application

Docket No. UF-336XC3D1

Serial No. 10/812,776

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 3731  
Applicant : David F. Muir  
Serial No. : 10/812,776  
Filed : March 29, 2004  
Conf. No. : 4996  
For : Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and In Vitro Nerve Tissue Culture

MS AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.97 and §1.98, the applicant would like to bring to the attention of the Examiner, the references cited in the following patent application:

U.S. Serial No. 10/218,864, filed August 13, 2002.

The subject application, Serial No. 10/812,776, claims the benefit under 35 USC §120 of the filing date of patent application Serial No. 10/218,864. The applicant respectfully requests that the copies of references supplied in the Information Disclosure Statements of the 10/218,864 application, as well as references cited during the prosecution thereof, be made of record in the 10/812,776 application. As copies of the references filed in the 10/218,864 application, and cited on the attached

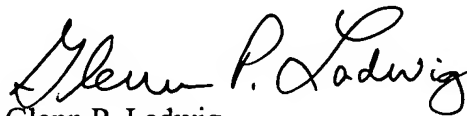
form PTO/SB/08, can be found in the 10/218,864 casefile, copies of those references are not provided herewith.

Please note that DE 19530556 (citation no. F9) is in a foreign language. In accordance with MPEP §609, an English language abstract of DE 19530556 and a foreign Examination Report citing DE 19530556 were submitted in the 10/218,864 application (citation nos. F10 and R56, respectively, on the attached form PTO/SB/08).

It is respectfully requested that the references cited in the 10/218,864 application be considered in the examination of the subject application and that their consideration be made of record.

The applicant respectfully asserts that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statements.

Respectfully submitted,



Glenn P. Ladwig

Patent Attorney

Registration No. 46,853

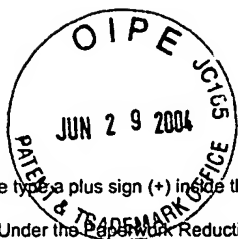
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Attachment: Form PTO/SB/08 (7 pages)



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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)  Sheet 1 of 7			<b>Complete if Known</b>	
			Application Number	10/812,776
			Filing Date	March 29, 2004
			First Named Inventor	David F. Muir
			Group Art Unit	3731
			Examiner Name	
			Attorney Docket Number	UF-336XC3D1

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	U1	2003/0068815	A1	Stone et al.	04-10-2003	All
	U2	2001/0039459	A1	Stone	11-08-2001	All
	U3	2001/0034043	A1	Su et al.	10-25-2001	All
	U4	6,455,309	B2	Stone	09-24-2002	All
	U5	6,267,786	B1	Stone	07-31-2001	All
	U6	6,231,608	B1	Stone	05-15-2001	All
	U7	6,093,563		Bennett et al.	07-25-2000	All
	U8	6,054,569		Bennett et al.	04-25-2000	All
	U9	5,997,863		Zimmermann et al.	12-07-1999	All
	U10	5,916,557		Berlowitz-Tarrant et al.	06-29-1999	All
	U11	5,716,617		Khandke et al.	02-10-1998	All
	U12	5,292,509		Hageman	03-08-1994	All
	U13	5,231,580		Cheung et al.	07-27-1993	All
	U14	4,933,185		Wheatley et al.	06-12-1990	All
	U15	4,696,816		Brown	09-29-1987	All
	U16	10/218,316		Muir (patent application)	08-13-2002	All
	U17	10/218,315		Muir (patent application)	08-13-2002	All

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	F1	WO	91/06573	A1	La Jolla Cancer Res. Foundation	05-16-1991	All	
	F2	WO	91/06303	A1	Case Western Reserve Univ.	05-16-1991	All	
	F3	WO	01/39795	A2	IBEX Tech., Inc.	06-07-2001	All	
	F4	WO	01/35977	A2	IBEX Tech., Inc.	05-25-2001	All	
	F5	EP	0 875 253	A2	Seikagaku Corp.	11-04-1998	All	
	F6	EP	0 613 949	A2	Maruha Corporation	09-07-1994	All	
	F7	EP	0 776 968	A1	Sumitomo Bakelite Co.	06-04-1997	All	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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	U18	6,200,564	B1	Lamont et al.	03-13-2001	All
	U19	6,214,978	B1	Truog et al.	04-10-2001	All
	U20	5,866,120		Karageozian et al.	02-02-1999	All
	U21	5,830,468		Bini	11-03-1998	All
	U22					
	U23					
	U24					
	U25					
	U26					
	U27					
	U28					
	U29					
	U30					
	U31					
	U32					
	U33					
	U34					

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	F8	EP	0 576 294	A2	Seikagaku Kogyo Kabushiki Kaisha	12-29-1993	All	
	F9	DE	19530556		Minuth Will Prof Dr	09-05-1996	All	
	F10	DE	19530556 (English abstract)		Minuth Will Prof Dr	09-05-1996	All	
	F11							
	F12							
	F13							
	F14							

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Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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### Complete if Known

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First Named Inventor	David F. Muir
Group Art Unit	3731
Examiner Name	
Attorney Docket Number	UF-336XC3D1

Sheet 3 of 7

### NON PATENT LITERATURE DOCUMENTS

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	R1	AGIUS, E. and P. COCHARD "Comparison of Neurite Outgrowth Induced by Intact and Injured Sciatic Nerves: A Confocal and Functional Analysis" <i>The Journal of Neuroscience</i> , January 1, 1998, 18(1):328-338.	
	R2	BENNETT, G.S. <i>et al.</i> "Chondroitinase ABC delivered to the site of a spinal cord injury upregulates GAP-43 expression in dorsal root ganglion neurons" <i>Society for Neuroscience Abstracts</i> , 2000, 26(1-2):Abstract no. 324.3 from 30 <sup>th</sup> Annual Meeting of the Society of Neuroscience, presented November, 2000; mailed to subscribers September, 2000.	
	R3	BERTOLOTTO, A. <i>et al.</i> "Immunohistochemical Localization of Chondroitin Sulfate in Normal and Pathological Human Muscle" <i>J Neurol Sci</i> , 1986, 73:233-244.	
	R4	BRADBURY, E.J. <i>et al.</i> "Chondroitinase ABC promotes functional recovery after spinal cord injury" <i>Nature</i> , April 2002, 416(6881):636-640.	
	R5	BRADBURY, E.J. <i>et al.</i> "Chondroitinase ABC promotes functional recovery after spinal cord injury" <i>Nature</i> , 2002, 416:636-640.	
	R6	BRADBURY, E.J. <i>et al.</i> "Chondroitinase ABC Delivered to the Site of a Spinal Cord Injury Upregulates GAP-43 Expression in Dorsal Root Ganglion Neurons" <i>Soc. Neurosci Abstr</i> , November 2000, abstract presented at the 30 <sup>th</sup> Annual Meeting of the Society of Neuroscience.	
	R7	BRAUNEWELL, K-H. <i>et al.</i> "Functional Involvement of Sciatic Nerve-derived Versican- and Decorin-like Molecules and other Chondroitin Sulphate Proteoglycans in ECM-mediated Cell Adhesion and Neurite Outgrowth" <i>Euro. J. Neurosci.</i> , 1995, 7:805-814.	
	R8	BRAUNEWELL, K-H. <i>et al.</i> "Up-regulation of a Chondroitin Sulphate Eptiope during Regeneration of Mouse Sciatic Nerve: Evidence that the Immunoreactive Molecules are Related to the Chondroitin Sulphate Proteoglycans Decorin and Versican" <i>Eur J Neurosci</i> , 1995, 7:792-804.	
	R9	BROWN, M.C. <i>et al.</i> "Further Studies on Motor and Sensory Nerve Regeneration in Mice With Delayed Wallerian Degeneration" <i>Eur J Neurosci</i> , 1994, 6:420-428.	
	R10	DANIELSEN, N. <i>et al.</i> "Predegeneration enhances regeneration into acellular nerve grafts" <i>Brain Res</i> , 1995, 681:105-108.	
	R11	DANIELSEN, N. <i>et al.</i> "Pre-degenerated nerve grafts enhance regeneration by shortening the initial delay period" <i>Brain Res</i> , 1994, 666:250-254.	
	R12	EVANS, P.J. <i>et al.</i> "Regeneration Across Cold Preserved Peripheral Nerve Allografts" <i>Microsurgery</i> , 1999, 19:115-127.	
	R13	EVANS, P.J. <i>et al.</i> "The Peripheral Nerve Allograft: A Comprehensive Review of Regeneration and Neuroimmunology" <i>Prog Neurobiol</i> , 1994, 43:187-233.	

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			Application Number	10/812,776	
			Filing Date	March 29, 2004	
			First Named Inventor	David F. Muir	
			Group Art Unit	3731	
Examiner Name					
Sheet	4	of	7	Attorney Docket Number	UF-336XC3D1

NON PATENT LITERATURE DOCUMENTS			
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	R14	EVANS, P.J. <i>et al.</i> "Cold Preserved Nerve Allografts: Changes in Basement Membrane, Viability, Immunogenicity, and Regeneration" <i>Muscle Nerve</i> , November 1998, 21:1507-1522.	
	R15	FAWCETT, J.W. and R.J. KEYNES "Peripheral Nerve Regeneration" <i>Annu Rev Neurosci</i> , 1990, 13:43-60.	
	R16	FERGUSON, T.A. and D. Muir "MMP-2 and MMP-9 Increase the Neurite-Promoting Potential of Schwann Cell Basal Laminae and Are Upregulated in Degenerated Nerve" <i>Mol Cell Neurosci</i> , 2000 16:157-167.	
	R17	FU, S.Y. and T. Gordon "The Cellular and Molecular Basis of Peripheral Nerve Regeneration" <i>Mol Neurobiol</i> , 1997, 14(1):67-116.	
	R18	GIANNINI, C. and P. DYCK "The Fate of Schwann Cell Basement Membranes in Permanently Transected Nerves" <i>J Neuropathol Exp Neurol</i> , 1990, 49(6):550-563.	
	R19	GORDON, L. <i>et al.</i> "Predegenerated nerve autografts as compared with fresh nerve autografts in freshly cut and pre-cut motor nerve defects in the rat" <i>J Hand Surg [Am]</i> , January 1979, 4(1):42-47.	
	R20	GULATI, A.K. "Evaluation of acellular and cellular nerve grafts in repair of rat peripheral nerve" <i>J Neurosurg</i> , January 1988, 68:117-123.	
	R21	HASAN, N. <i>et al.</i> "The influence of predegenerated nerve grafts on axonal regeneration from prelesioned peripheral nerves" <i>J Anat</i> , 1996, 189:293-302.	
	R22	IDE, C. <i>et al.</i> "Schwann Cell Basal Lamina and Nerve Regeneration" <i>Brain Res</i> , 1983, 288:61-75.	
	R23	JONES, L.L. <i>et al.</i> "Neurotrophic factors, cellular bridges and gene therapy for spinal cord injury" <i>J. Physiology</i> , 2001, 533.1:83-89.	
	R24	KHERIF, S. <i>et al.</i> "Matrix metalloproteinases MMP-2 and MMP-9 in denervated muscle and injured nerve" <i>Neuropathol Appl Neurobiol</i> , 1998, 24:309-319.	
	R25	KREKOSKI, C.A. <i>et al.</i> "Metalloproteinase-Dependent Predegeneration <i>In Vitro</i> Enhances Axonal Regeneration within Acellular Peripheral Nerve Grafts" <i>J. Neuroscience</i> , December 2002, 22(23):10408-10415.	
	R26	KREKOSKI, C.A. <i>et al.</i> "Axonal Regeneration into Acellular Nerve Grafts Is Enhanced by Degradation of Chondroitin Sulfate Proteoglycan" <i>The Journal of Neuroscience</i> , August 15, 2001, 21(16):6206-6213.	

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	R27	LA FLEUR, M. <i>et al.</i> "Basement Membrane and Repair of Injury to Peripheral Nerve: Defining a Potential Role for Macrophages, Matrix Metalloproteinases, and Tissue Inhibitor of Metalloproteinases-1" <i>J. Exp. Med.</i> , December 1996, 184:2311-2326.	
	R28	LANGLEY, J.N. and H.K. ANDERSON "The Union of Different Kinds of Nerve Fibres" <i>J Physiol</i> , 1904, 31:365-391.	
	R29	LASSNER, F. <i>et al.</i> "Preservation of Peripheral Nerve Grafts: A Comparison of Normal Saline, HTK Organ Preservation Solution, and DMEM Schwann Cell Culture Medium" <i>J Reconstr Microsurg</i> , 1995, 11:447-453.	
	R30	LEMONS, M.L. <i>et al.</i> "Chondroitin Sulfate Proteoglycan Immunoreactivity Increases Following Spinal Cord Injury and Transplantation" <i>Exper. Neuro.</i> , 1999, 160:51-65.	
	R31	LEVI, A. <i>et al.</i> "Cold Storage of Peripheral Nerves: An In Vitro Assay of Cell Viability and Function" <i>Glia</i> , 1994, 10:121-131.	
	R32	MCKEON, R.J. <i>et al.</i> "Injury-Induced Proteoglycans Inhibit the Potential for Laminin-Mediated Axon Growth on Astrocytic Scars" <i>Exp. Neuro.</i> , 1995, 136:32-43.	
	R33	MCKEON, R.J. <i>et al.</i> "Reduction of Neurite Outgrowth in a Model of Glial Scarring following CNS Injury is Correlated with the Expression of Inhibitory Molecules on Reactive Astrocytes" <i>J. Neurosci.</i> , 1991, 11(11):3398-3411.	
	R34	MOON, L. <i>et al.</i> "Regeneration of CNS axons back to their target following treatment of adult rat brain with chondroitinase ABC" <i>Nature Neuroscience</i> , May 2001, 4(5):465-466.	
	R35	MUIR, D.F. "Enzymatic De-Inhibition of Axonal Regeneration", Abstract, Grant No. 1R01NS037901-01A1, Computer Retrieval of Information on Scientific Projects (CRISP) database, <a href="http://crisp.cit.nih.gov/">http://crisp.cit.nih.gov/</a> , maintained by the Office of Extramural Research at the National Institutes of Health (NIH), April 2, 2001.	
	R36	MUIR, D. <i>et al.</i> "Schwannoma Cell-derived Inhibitor of the Neurite-promoting activity of Laminin" <i>J. Cell Biol.</i> , November 1989, 109:2353-2362.	
	R37	NADIM, W. <i>et al.</i> "The role of Schwann cells and basal lamina tubes in the regeneration of axons through long lengths of freeze-killed nerve grafts" <i>Neuropathol Appl Neurobiol</i> , 1990, 16:411-421.	
	R38	OCHI, M. <i>et al.</i> "Nerve Regeneration in Predegenerated Basal Lamina Graft: The Effect of Duration of Predegeneration on Axonal Extension" <i>Exp Neurol</i> , 1994, 128:216-225.	
	R39	OLMARKER, K. <i>et al.</i> "Chondroitinase ABC (Pharmaceutical Grade) for Chemonucleolysis" <i>Spine</i> , 1996, 21:1952-1956.	

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R40	SALONEN, V. <i>et al.</i> "Laminin in traumatized peripheral nerve: basement membrane changes during degeneration and regeneration" <i>J Neurocytol</i> , 1987, 16:713-720.	
	R41	SHUBAYEV, V.I. and R.R. MYERS "Upregulation and interaction of TNF $\alpha$ and gelatinases A and B in painful peripheral nerve injury" <i>Brain Res</i> , 2000, 855:83-89.	
	R42	SIEBERT, H. <i>et al.</i> "Matrix Metalloproteinase Expression and Inhibition After Sciatic Nerve Axotomy" <i>J Neuropathol Exp Neurol</i> , January 2001, 60(1):85-93.	
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	R49	WANG, G-Y. <i>et al.</i> "The role of laminin, a component of Schwann cell basal lamina, in rat sciatic nerve regeneration within antiserum-treated nerve grafts" <i>Brain Res</i> , 1992, 570:116-125.	
	R50	YAMADA, T. <i>et al.</i> "Selective localization of gelatinase A, an enzyme degrading $\beta$ -amyloid protein, in white matter microglia and in Schwann cells" <i>Acta Neuropathol (Berl)</i> , 1995, 89:199-203.	
	R51	YICK, L-W. <i>et al.</i> "Chondroitinase ABC promotes axonal regeneration of Clarke's neurons after spinal cord injury" <i>NeuroReport</i> , 2000, 11(5):1063-1067.	
	R52	ZUO, J. <i>et al.</i> "Degradation of Chondroitin Sulfate Proteoglycan Enhances the Neurite-Promoting Potential of Spinal Cord Tissue" <i>Exp Neurol</i> , 1998, 154:654-662.	

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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### Complete if Known

Application Number	10/812,776
Filing Date	March 29, 2004
First Named Inventor	David F. Muir
Group Art Unit	3731
Examiner Name	
Attorney Docket Number	UF-336XC3D1

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	R53	ZUO, J. <i>et al.</i> "Chondroitin Sulfate Proteoglycan with Neurite-Inhibiting Activity Is Up-regulated following Peripheral Nerve Injury" <i>J Neurobiol</i> , 1998, 34:41-54.	
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	R55	ZUO, J. <i>et al.</i> "Regeneration of Axons after Nerve Transection Repair Is Enhanced by Degradation of Chondroitin Sulfate Proteoglycan" <i>Exp. Neurology</i> , 2002, 176:221-228.	
	R56	New Zealand Examination Report dated May 20, 2004; cited in counterpart New Zealand application no. 531129.	
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